

Applicant : Don Fishbein  
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REMARKS

Claims 30-45 are pending in the subject application. By this amendment applicant has amended claims 30-35.

Support for the amendments to claim 30 may be found in the specification at, inter alia, page 2, lines 7-8; page 4, line 24; page 7, lines 14-16; page 9, lines 22-25; page 12, line 7; page 12, lines 21-22; and page 15, lines 23-26.

Support for the amendments to claim 31 may be found in the specification at, inter alia, page 10, lines 4-5.

Support for the amendments to claims 32-33 may be found in the specification at, inter alia, page 10, lines 4-5 and page 10, lines 7-8.

Support for the amendments to claim 34 may be found in the specification at, inter alia, page 10, lines 4-5 and page 17, line 10.

Support for the amendments to claim 35 may be found in the specification at, inter alia, page 10, lines 4-5.

Applicant maintains that these amendments raise no issue of new matter. Accordingly, claims 30-45 will be pending upon entry of this Amendment.

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**Claims Rejected Under 35 U.S.C. §103(a)**

In the June 30, 2006 Office Action, the Examiner rejected claims 30-43, 36-40, 42 and 43 under 35 U.S.C. §103(a) as allegedly obvious over Clark et al. (U.S. Patent No. 6,011,023) in view of Roberts et al. (U.S. Patent No. 4,112,123). The Examiner stated, inter alia, that Clark et al. teach administration of angiostatic steroids in the treatment of burns and alleged that Clark et al. cites oxandrolone as a compound to be used in such treatment (see claim 1 of Clark et al.). The Examiner also stated that Roberts et al. teaches that abnormal catabolic states can be induced by traumas such as a burn and also teaches a nutritionally balanced food composition for oral ingestion by patients with such abnormal catabolic states.

In response, applicant respectfully traverses the Examiner's rejection. Applicant notes Clark et al. specifically teaches not using oxandrolone in the method claimed in that patent. Applicant draws the Examiner's attention to the "also excepted from the compounds..." language at col. 24, line 61 preceding the recitation of "oxandrolone" at col. 25, line 27. Thus, oxandrolone is specifically excluded. Roberts et al. does not teach or suggest using angiostatic steroids at all. Taken in combination, Clark et al. and Roberts et al. do not teach or suggest using oxandrolone in a method of promoting weight gain, in contrast to applicant's invention as claimed in claims 30-45. Thus, the cited references combined do not teach or suggest every element of claim 30 and claims 31-43, 36-40, 42 and 43

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dependent therefrom. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

The Examiner also rejected claims 30-34, 36-41 and 42-45 under 35 U.S.C. §103(a) as allegedly obvious over Clark et al. (U.S. Patent No. 6,011,023) in view of Roberts et al. (U.S. Patent No. 4,112,123) and Almada et al. (U.S. Patent 5,726,146). The Examiner stated that the teachings of Clark et al. and Roberts et al. are as indicated above. The Examiner further stated that Alamada et al. teach dietary supplement formulations containing protein source(s) which increase lean body mass without concomitant increase of body fat mass.

In response, applicant respectfully traverses the Examiner's rejection. Applicant notes Clark et al. specifically teaches not using oxandrolone in the method claimed in that patent. Applicant draws the Examiner's attention to the "also excepted from the compounds..." language at col. 24, line 61 preceding the recitation of "oxandrolone" at col. 25, line 27. Thus, oxandrolone is specifically excluded. Neither Roberts et al. or Almada et al. teach or suggest using angiostatic steroids at all. Taken in combination, Clark et al., Roberts et al. and Almada et al. do not teach or suggest using oxandrolone in a method of promoting weight gain, in contrast to applicant's invention as claimed in claims 30-45. Thus, the cited references combined do not teach or suggest every element of claim 30 and claims 31-34, 36-41 and 42-45 dependent therefrom. Accordingly,

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applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

The Examiner also rejected claims 30-34, 36-40, 42 and 43 under 35 U.S.C. §103(a) as allegedly obvious over Clark et al. (U.S. Patent No. 6,011,023) in view of Roberts et al. (U.S. Patent No. 4,112,123) and Folkman et al. (U.S. Patent 5,021,404). The Examiner stated that the teachings of Clark et al. and Roberts et al. are as indicated above. The Examiner further stated that Folkman et al. teach sustained formulations of angiostatic steroids.

In response, applicant respectfully traverses the Examiner's rejection. Applicant notes Clark et al. specifically teaches not using oxandrolone in the method claimed in that patent. Applicant draws the Examiner's attention to the "also excepted from the compounds..." language at col. 24, line 61 preceding the recitation of "oxandrolone" at col. 25, line 27. Thus, oxandrolone is specifically excluded. Roberts et al. does not teach or suggest using angiostatic steroids at all, and Folkman et al. does not teach oxandrolone. Taken in combination, Clark et al., Roberts et al. and Folkman et al. do not teach or suggest using oxandrolone in a method of promoting weight gain, in contrast to applicant's invention as claimed in claims 30-45. Thus, the cited references combined do not teach or suggest every element of claim 30 and claims 31-34, 36-40, 42 and 43 dependent therefrom. Accordingly, applicant respectfully

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requests that the Examiner reconsider and withdraw this ground of rejection.

**Claims Rejected Under 35 U.S.C. §112, Second Paragraph**

In the June 30, 2006 Office Action, the Examiner rejected claims 30-45 under 35 U.S.C. §112, second paragraph, as allegedly indefinite in that claim 30 recites "a therapeutically effective amount of oxandrolone" but does not recite the desired effect. The Examiner stated that to overcome this rejection it is suggested that after the phrase a "therapeutically effective amount of oxandrolone" the phrase "effective for promoting weight gain in said patient" should be inserted.

In response, applicant respectfully traverses the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicant has herein amended claim 30 to recite the phrase suggested by the Examiner. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

In accordance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following documents which are listed on Form PTO-1449 (**Exhibit A**) and are also listed below. Copies of references 2-34 are attached hereto as Exhibits 1-33. Reference no. 1 is a U.S. patent and no copy is attached hereto as permitted under 37 C.F.R. §1.98(a)(2)(ii).

Applicant is filing this Supplemental Information Disclosure Statement under C.F.R. §1.97(c)(2), before the mailing of a final office action on the merits accompanied by the fee of ONE HUNDRED EIGHTY DOLLARS (\$180.00) set forth in 37 C.F.R. §1.17(p). Accordingly, applicant requests that this Supplemental Information Disclosure Statement be considered.

1. U.S. Patent No. 5,340,586, issued August 1994, Pike;
2. European Patent Application 0222385, February 1993;
3. Protest Under 37 C.F.R. §1.291(a) filed on October 18, 1999 with the United States Patent and Trademark Office in connection with U.S. Serial No. 08/244,988, pp. 1-7, including a cover sheet, a Form PTO-1449, and Exhibits A-E;
4. March 2, 2000 Decision on Protest Under 37 C.F.R. §1.291(a) in connection with U.S. Serial No. 08/244,988, pp. 1-2, including a cover sheet, a Form PTO-892, Information on

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Submitting an IDA (2 pages), and a copy of 21 C.F.R. 312 (39 Pages);

5. Aroonsakul, Chemical Abstracts, vol. 115: 151902q, 1988;
6. Bailey, R.O., Turok, D.I., Jaufmann and Singh, J.K. (1987). Myositis and acquired immunodeficiency syndrome. Hum. Path. 18:749-751;
7. Berger, J.R., (1991). Personal communication between Dr. Berger and Dr. Dudley of Gynex (letter dated July 6, 1991);
8. Bessen, L.J., Greene, J.B., Louie, E., Seitzman, P., and Weinberg, H. (1988). Severe polymyositis-like syndrome associated with zidovudine therapy in AIDS and ARC. N. Eng. J. Med. 318:708;
9. Blizzard, R.M., Hindmarsh, P.C. and Stanhope, R. (1991). Oxandrolone therapy: 25 years experience. Growth, Genet. Hor. 7:1-7;
10. Boris, et al., Chemical Abstracts, vol. 74: 72305d, 1971;
11. Chelbowski, R.T., Grosvenor, M.B., Bernhard, N.H., Morales, L.S. and Bulcavage, L.M. (1989). Nutritional status, gastrointestinal dysfunction and survival in patients with AIDS. Am. J. Gastroent. 84:1288-1293;

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12. Chernoff, D. (1990). Myositis in HIV-infected patients. In the AIDS Knowledge Base, Cohen, P.T., Sande, M.A. and Volberding, P.A. (eds.). Waltham, The Medical Publishing Group, pp. 5.14. 1-2;
13. Dalakas, M.C., Pezeshkpour, G.H., Gravel, M. and Sever, J.L. (1986). Polymyositis associated with AIDS retrovirus. J. Amer. Med. Assoc. 256:2381-2383;
14. Gonzales, M.F., Olney, R.K., So, Y.T., Greco, C.M., et al. (1988). Subacute structural myopathy associated with human immunodeficiency virus infection. Arch. Neurol. 45:585-587;
15. Gorard, D.A., Henry, K., and Guilloff, R.J. (1988). Necrotizing myopathy and zidovudine. Lancet. 1:1050-1051;
16. Hellerstein, M.K., J. Mudie, H. and Viteri, F. (1990). Current Approach to the treatment of human immunodeficiency virus-associated weight loss: pathophysiologic considerations and emerging management strategies. Sem. Oncol;
17. Hughes, B.J. and Kreig, M. (1988). Steroid receptors and the muscular system. In, Steroid Receptors and Disease, Sheridan, P.J. Blum, K. and Trachtenberg, M.C. (eds). Marcel Dekker, Inc., New York, pp. 415-433;
18. Jones, R.W.A., El Bishti, M.M., Bloom, S.R., Burke, J., Carter, J.E., et al (1980). The effects of anabolic steroids



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on growth, body composition, and metabolism in boys with chronic renal failure on regular hemodialysis. J. Pediat. 97:559-566;

19. Karim et al., (1973), "Oxandrolone Disposition and Metabolism In Man," 80 *Chemical Abstracts*: 10551;
20. Kotler, D.P., Wang, J. and Pierson, R.N. (1985). Body composition studies in patients with acquired immunodeficiency syndrome. Am. J. Clin. Nutr. 42:1255-1265;
21. Kotler, D.P., Tierney, A.R., Wang, J., and Pierson, R.N. (1989). Magnitude of body-cell-mass depletion and the timing of death wasting in AIDS. Am. J. Clin. Nutr. 50:444-447;
22. Lone, et al., *Chemical Abstracts*, vol. 107: 174950c, 1987;
23. Masse, R.B.H., Ayotte, C. and Dugal, R. (1989). Studies on anabolic steroids II - Gas chromatographic/mass spectrometric characterization of oxandrolone urinary metabolites in man. *Biomed. Environ. Mass Spectrom.* (England) 18:429-438;
24. Mendenhall, C.L., Anderson, S., Garcia-Pont, P., Goldberg, S., et al. (1984). Short-term and long-term survival in patients with alcoholic hepatitis treated with oxandrolone and prednisolone. N. Eng. J. Med. 311:1464-1470;

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25. Mendenhall, C.L., Grossman, C.J., Roselle, G.A., et al. (1990). Anabolic steroids effects on immune function: differences between analogues. *J. Steroid Biochem. Molec. Biol.* 37:71-76;
26. Metcalf, et al., (1965), 62 *Chemical Abstracts*: 45397;
27. Metcalf et al., (1965), "A Quantitative Expression For Nitrogen Retention With Anabolic Steroids. IV. Oxandrolone," *Metabolism*, 14(1) pp. 59-66;
28. Meyers, F.H., Jawetz, E. and Goldfien, A. (1980). Review of Medical Pharmacology. California: Lange Medical Publications, p. 415;
29. Morton, J.J.P., and M.H. Malone, (1972), "Evaluation of Vulnerary Activity by an Open Wound Procedure in Rats", *Arch. Int. Pharmacodyn*, Vol. 196, pp. 117-126;
30. O'Shea, et al., *Chemical Abstracts*, vol. 74: 75106a, 1971;
31. "Orphan Drug for HIV Wasting Syndrome", *Am. Fam. Physician* (1991), Vol. 44, page 1889;
32. Pan, C.S., Inadomi, D.W., Laidlaw, S.A., Jones, M.R., and Kopple, J.D. (1984). Oxandrolone enhances muscle protein synthesis in acutely uremic rats. *Kidney Intl.* 25:236;

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33. Simpson, D.M. and Bender, A.N. (1988). Human immunodeficiency virus-associated myopathy: analysis of 11 patients. *Ann. Neurol*; and
34. Tchekmedyian, (1993), "Clinical Approaches to Nutritional Support in Cancer," *Current Opinion in Oncology*, Vol. 5, pp. 633-638.

Applicant requests that the Examiner review the references and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

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No fee, apart from the total enclosed fee of \$300.00, including \$180.00 fee for submitting a Supplemental Information Disclosure Statement and \$120.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment and Supplemental Information Disclosure Statement. However, if any other fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
<i>Gary J. Gershik</i> John P. White Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992	<i>10/26/06</i> Date

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